

## **REMARKS**

### **Status of Claims**

Upon entry of this amendment, only independent claim 43 will be pending in this application. Claims 44, 46-48, and 50-59 are cancelled without prejudice or disclaimer of Applicant's right to pursue the canceled subject matter in this or a related application. The dependent claims are canceled solely to simplify the issues and focus the prosecution on the patentability of the sole independent claim.

### **Claim Rejections**

#### **Obviousness**

The Examiner rejects claims 43, 44, 46-48, and 50-59 under 35 U.S.C. §103(a) as obvious over Zastrow, et al. (WO 99/38483, abstract) in view of Lapinet, et al. (U.S. Patent No. 3,978,213), Tomina, et al. (U.S. Patent No. 5,314,873), Peyronel, et al. (WO 92/04420, abstract), Chambers, et al. (WO 97/27835), Moller, et al. (U.S. Patent No. 4,496,536), Tanaka (JP 09030946) and Babish, et al. (WO 96/17605) for reasons already of record. Applicants traverse these rejections.

Independent claim 43 is the only remaining claim in the application. It is directed to the topical application of andrographolide or a derivative to an area of the skin affected by wrinkles and/or fine lines in order to improve the appearance thereof. Several of the references cited by the Examiner presumably are relied upon only in relation to features of the dependent claims, although the Examiner does not explain which combination of references are applied to which claims. Nevertheless, Applicants have canceled the dependent claims so examination may focus on the treatment of wrinkles with andrographalide, as recited in independent claim 1. Many of the references cited by the Examiner have no relevance whatsoever to the patentability of this method. In fact, of the references cited by the Examiner, only Tanaka relates to topical application of andrographolide compounds to the skin.

However, independent claim 43 cannot be obvious over Tanaka because Tanaka does not teach or suggest application of andrographolide or its derivatives to treat skin with wrinkles and/or fine lines nor does Tanaka teach a use of the same composition that would inherently practice the instantly claimed method. Applicants submit that this case is controlled by the

inherency framework explained by the Court of Appeals for the Federal Circuit in Perricone v. Medicis Pharm. Corp., 432 F.3d 1368 (Fed. Cir. 2005). In that case, the Court held that the prior art did not invalidate claims directed toward application of a composition to sunburned skin since the prior art only disclosed application of the composition to skin in general, not sunburned skin in particular. Id., at p. 1379. Here, the Examiner cites Tanaka as teaching extracts of “Andrographis in oil-in-water preparations for skin lightening which inhibits melanin formation and tyrosinase.” OA, at p. 3. However, the Examiner has offered no rationale or proof that the skin treated in Tanaka suffered from wrinkles and/or fine lines and Tanaka cannot, therefore, inherently disclose the use of Andrographis extracts to treat skin with wrinkles and/or fine lines.

Furthermore, neither tyrosinase nor melanin are alleged by the Examiner to be implicated in wrinkles and/or fine lines and it is not seen that the inhibition of tyrosinase or melanin with extracts of Andrographis, as taught by Tanaka, would have motivated one skilled in the art, with a reasonable expectation of success, to use andrographolide compounds to treat wrinkles, etc. Accordingly, absent an understanding that andrographolide is effective in reducing wrinkles and/or fine lines, there would have been no motivation to employ andrographolide to treat wrinkles and/or fine lines. Since Tanaka does not remotely teach or suggest the use of andrographolide compounds in reducing the appearance of wrinkles and/or fine lines, reconsideration and withdrawal of this ground of rejection is respectfully requested.

**CONCLUSION**

Applicants respectfully submit that the instant application is in condition for allowance. Entry of the amendments and an action passing this case to issue is therefore respectfully requested. In the event that a telephone conference would facilitate examination of this application in any way, the Examiner is invited to contact the undersigned at the number provided.

Respectfully submitted,

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